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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3884n

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

Robert A. Rabiner
President
OmniSonics Medical Technologies, Inc.
66 Concord Street Suite A
Wilmington, MA 01887

JUN 22 2000

Dear Mr. Rabiner:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed the Internet website of OmniSonics Medical Technologies, Inc. (OmniSonics) at www.omnisonics.com. The website contains inappropriate claims for the company's ultrasonic probes, cleared by FDA for marketing pursuant to its review of the company's premarket notification submission, k993628. The probes are devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The probes were cleared with the following intended use language:

"The intended use of the OmniSonics Ultrasound Probes is the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic. The OmniSonics Ultrasonic Probes are used in conjunction with the OmniSonics Ultrasonic Surgical System.

The OmniSonics Ultrasonic Probes are designed to be introduced through natural body cavities or surgical incisions through introducers, needle or trocars, catheters, sheaths or other devices with lumens having an inside diameter larger than the outside diameter of the probe."

OmniSonics did not receive clearance for the use of its probes for the treatment of specific medical conditions or for use in specific body sites. Your website contains the following claims that did not receive clearance from the agency:

1. "Omnisonics [sic] **Technologies for Treatment of Benign Prostate Hyperplasia"**

The device was not specifically cleared for use in the treatment of benign prostate hyperplasia (BPH). The claims on your website page that begins, "Unique Features of the OmniSonics UltraSonic System" has a list of "benefits" that the company attributes to the treatment with its device of BPH. That page also makes claims about the histology of the tissue treated by the device.

2. "OmniSonics Ultrasonic Technologies For Gynecology"

The page includes claims for use of the device in treating "Disfunctional [sic] Uterine Bleeding, benign uterine pathologies and fibroids.

3. "Omnisonics [sic] **Technologies for CardioVascular and Peripheral Vascular Procedures"**

The page includes claims for the device as a "non-surgical system for the removal of blood clots from peripheral artery grafts and vein grafts" and as a tool for "the removal of plaque from the carotid arteries."

Your web site also includes an Oct 6, 1999 PR Newswire press release that makes similar misleading representations concerning the use of your probes. The agency's regulations at 21 CFR 801.4 provide that the intended use of the device is the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. The objective intent may be shown by, for example, labeling claims, advertising matter or oral or written statements of such responsible persons or their representatives. None of the three specific uses provided above is included in the intended use statement for the device.

The claims have caused your company's device to be misbranded and adulterated within the meaning of sections 502(o) and 501(f)(1)(B), respectively, of the Act. The product is misbranded within the meaning of section 502(o) because information respecting the device was not provided to the agency as required by section 510(k) of the Act. It is adulterated within the meaning of section 501(f)(1)(B) because claims for uses for which the device has not been determined to be substantially equivalent to a predicate device make the device a class III device without either an approved premarket approval application, as required by section 515 of the Act or an approved investigational device exemption, as required by section 520(g) of the Act. In addition, several of the claims that you have made specifically require a PMA or a new 510(k) with clinical data. Marketing the device for use in peripheral vascular procedures generally requires a 510(k) with clinical data. The endometrial ablation claim could require submission of a PMA. The fibroids claim would most likely require a 510(k) and clinical data. The urological claims require a premarketing submission, probably a 510(k) but possibly a PMA. Clinical data would be required for a 510(k). Use of the device in the peripheral vascular use would require submission of a 510(k) with clinical data. Use of the probe to remove plaque from the carotid arteries would require submission of either a 510(k) or a PMA, and clinical data.

This letter is not intended to be an all-inclusive list of deficiencies associated with OmniSonics' devices. It is your responsibility to ensure adherence to each requirement of the Act and the regulations. The specific violations noted in this letter may also be reflected in other promotion and advertising materials used by your company. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps that you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Direct your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New England District Office. Please send a copy of your response to the District Director, New England District Office, Food and Drug Administration (HFR-NE240), One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Sincerely yours,

Byron Tart for

Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

prepared: Dwolf: 6/14/00
revised: B Tart: 6/15/00
consult: Y Pak:6/15/00
consult: G Kroehling: 6/16/00
consult: J Baxley (6/20/00)
consult: C Sloan: (6/20/00
consult: C Pollard (6/20/00)
consult: New England District (6/22/00)
final: D Wolf: 6/23/00

bcc:

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HFI-35 (purged cc)
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HFZ-305 (precedent file)
HFZ-306 (Cathy Condon)
HFZ-323 (G Kroehling)
HFZ-452 (C Sloan)
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HFZ-471 (Y Pak, C Pollard)